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April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276 (Registration)

Dear Sir or Madam:

The American Frozen Food Institute ("AFFI") welcomes this opportunity to comment on the U.S. Food and Drug Administration's ("FDA") proposed rule to implement the food facility registration provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act" or "Act"). AFFI is the national trade association representing frozen food manufacturers, their marketers and suppliers. AFFI's 511 member companies are responsible for approximately 90 percent of the frozen food processed annually in the United States, valued at more than $60 billion. AFFI members are located throughout the country and are engaged in the manufacture, processing, transportation, distribution, and sale of products nationally and internationally.

AFFI appreciates the agency's apparent willingness to work closely with industry in developing a final rule that would further the Bioterrorism Act's goal of securing the American food supply against acts of intentional contamination. Open and receptive communication between FDA and industry is of utmost importance given that the Act provides the agency with very little time to implement the most significant expansion of FDA's authority with regard to foods in decades.

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AFFI is pleased to see that the registration proposal incorporates several suggestions made in our initial comments to the agency. The proposed provision to allow companies, operating from their corporate headquarters location, to submit registrations on behalf of all of the facilities they own, operate, or for which they act as an agent will greatly reduce the registration burden on entities that own or operate multiple facilities. Moreover, AFFI appreciates the proposal's clarification that the statute's requirement to submit "trade names" refers to the trade names of the registering entity only, not its products.

AFFI is concerned, however, that the proposal to require submission of "FDA product code" categories for all foods in a registered facility would unduly burden the food industry, while actually hindering, rather than fostering, an effective response to a potential or actual terrorist threat. Another significant concern arises from the agency's request for comment on circumstances under which a facility's registration should be revoked or considered null and void. In response, AFFI notes that the Bioterrorism Act does not provide FDA with authority to revoke complete and truthful registrations that have been properly filed with the agency.

These concerns and additional comments on how to improve the registration process without unduly burdening commerce are discussed in detail below. Many of these comments echo concerns discussed in AFFI's initial comments to FDA submitted prior to the publication of the proposal, as well as those submitted to OMB regarding the paperwork burden associated with the registration proposal.

I. FDA Should Not Require Submission of General Food Categories

As stated in our initial comments to FDA, AFFI strongly urges the agency to refrain from requiring registrants to submit general food category information under Section 170.3 of the regulations. The agency preliminarily concludes that such information is "necessary for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency . . ." Required submission of general food categories, however, would impose enormous costs on industry not justified by reason of the ability to focus communications, which AFFI believes would actually hinder an effective response to an actual or potential bioterrorist threat to the food supply. Our position remains the same despite FDA's efforts to make the proposition more workable through use of the common code categories found in FDA's product code builder.

A. Benefit of Food Category Information is Highly Questionable

More importantly, it is unclear how access to general food category information would be useful in enhancing the protection against terrorist threats to our food supply. As mentioned above, FDA tentatively concludes that general product category information is necessary "for a quick, accurate, and focused response to a bioterrorist incident or other food-related emergency." In addition, agency personnel at the January 29, 2003, public meeting held to introduce the proposal emphasized the importance of using the product category information for "targeted communication." AFFI believes, however, that focused communication related to bioterrorist threats has the potential to lead to significant omissions, which could hinder efforts to respond to the threats.

Despite industry efforts, because of the dynamic nature of the food supply, the general food category information provided in a registration form likely would never be completely current, underscoring the danger of focused communications. This is especially true with respect to large facilities producing many diverse products. If FDA were to target communications to only those facilities that reported foods in a specific category, the agency might fail to notify the larger facilities that produce affected food products, but have yet to submit updated food product categories. Since the larger facilities produce high volumes of products with nationwide distribution, focused communications could cause affected products to land in the hands of unwitting consumers across the nation. Indeed, if focused communications could eliminate the harm associated with dangerous foods, press releases would not be needed for Class I recalls.

Further in that regard, it is important to recognize that one food manufacturer's finished product is another's ingredient. Many of the proposed product categories encompass foods used as ingredients in countless finished food products (e.g., cheese, flour, and dried milk). Communications targeted at facilities that produce discrete food categories would fail to apprise manufacturers of potential threats to the thousands of finished products in which the affected foods are used as ingredients.

The only way to ensure that the manufacturers, processors, packers, and holders of all affected foods are on notice of potential threats to their products is to inform the entire food industry of the general threat to a particular segment. Affected facilities would then work directly with the agency in preparing for and responding to direct threats, while all facilities would be on heightened alert. It is of utmost importance that every facility knows of potential threats to the food supply, particularly because most bioterrorism tools applicable to food products are indiscriminate and could be used to contaminate the vast majority of foods.

B. Submission of Food Categories Would Impose Enormous Costs on Industry

Hundreds of thousands of facilities manufacture, process, pack, and hold tens of thousands of different types of products. The nature of those products, moreover, changes constantly over time. Assigning general food categories to this vast array of products, and updating that information with FDA, would impose costs on the food industry far in excess of FDA's estimated costs, without improving the agency's ability to protect the public.

Specifically, FDA estimates that removing the proposed requirement to submit product category information would decrease the amount of time necessary to fill out the registration form from one hour to 45 minutes. Although this may hold true for single product companies/facilities, it understates significantly the time it would take food companies/facilities that make a variety of products to complete registration forms.

Under the FDA proposal, facilities that manufacture, process, pack or hold hundreds or thousands of different food products would have to review each product to determine the appropriate FDA product code category. The applicable FDA product code is difficult to determine for many foods, however, due to the sometimes redundant and counter-intuitive nature of the code. For instance, ready-to-eat pudding belongs in the "bakery products, dough mixes, or icings" category, while pudding mixes belongs in the "gelatin, rennet, pudding mixes, or pie fillings" category. Understanding these subtle distinctions may take hours for certain products. Our members have estimated that it would take larger facilities days to determine all of the applicable FDA product codes, so that the proper general product code categories could be specified.

Moreover, the categories would be subject to constant fluctuation as the nature of the products produced at larger facilities changes constantly over time. This would require regular registration updates for facilities with more diverse product lines, imposing undue burden on both FDA and industry not considered in the agency's cost estimates. For example, one large food processor reported to AFFI that the most optimistic scenario would require updates to food category information on a monthly basis. Tracking frequent product line movement would require the company to devote a full-time employee to the task.

C. Summary/Suggestions

In summary, AFFI believes that the stated purpose for requiring submission of food category information (i.e., to allow for targeted communications) would likely lead to significant omissions and, in turn, potentially fatal consequences. Moreover, the cost to industry of tracking this information would be enormous. AFFI, therefore, strongly urges FDA to eliminate the proposed requirement to submit general food categories.

In the alternative, the agency should, at a minimum, revise the registration form to allow a company submitting registrations on behalf of numerous facilities to indicate that the company's facilities, when considered together, manufacture, process, pack, and/or hold products in "most/all food product categories." Companies that represent a limited number of food products should be allowed to list the food categories represented by company operations without reference to specific facilities. This would greatly ease the burden on large food companies associated with tracking the constant changes to the general food categories at their various facilities.

Moreover, AFFI believes that the addition of this catchall category would actually increase the effectiveness of FDA communications of potential or actual bioterrorist threats. This is because most large companies are likely to submit a single emergency contact and preferred mailing address for each of the many facilities they own. That contact position, likely located at the company's headquarters, would possess the necessary information to determine which of the company's hundreds or thousands of facilities would be affected by the communicated threat.

II. FDA Should Provide for Submission of Alternate Emergency Contact Information

The information that would best assist FDA in its efforts to rapidly communicate actual or potential bioterrorist incidents to industry is emergency contact information. For this reason, AFFI requests that the agency expand the registration form to provide registrants with the option of providing an alternative emergency contact to serve as "back-up" in the event that the primary contact is not available.

III. FDA Should Clarify the Scope of the Registration Requirement With Respect to Vehicles

AFFI requests FDA to clarify in the final rule that the registration requirement does not apply to vehicles (e.g., trucks, ocean carriers, airplanes, barges, rail cars, and trailers) regardless of whether they temporarily store food. Although FDA has stated publicly that it had not intended the proposed registration requirement to cover vehicles used to transport food, this position is not clear from the proposal.

Specifically, the proposed definition of "facility" includes "a mobile facility traveling to multiple locations that . . . holds food for consumption in the U.S." In turn, the agency proposes to define "holding" as "storage of food." Certain trucks and ocean carriers are used not only to transport food, but also to store it, on occasion, for several days to weeks. It appears, therefore, that the proposal would require such vehicles to register with FDA as a "mobile facility" that "holds" food.

In the Conference Report to the Bioterrorism Act, the Managers explicitly state that the registration requirement is not intended to apply to "motor carriers" that receive, carry, *hold*, or deliver food "in the usual course of business as carriers." / Congress likely relied on the apparent difficulty in implementing and enforcing the registration requirement on vehicles in providing for their exemption. For instance, vehicles do not have a fixed address, nor do they always transport the same types of food. Accordingly, AFFI urges the agency to revise the definition of facility to give effect to the Congressional intent and clarify that vehicles that hold and transport food in their usual course of business are not required to register.

IV. Revocation or Nullification of Registrations

AFFI emphasizes that the Bioterrorism Act does not provide FDA with the authority to revoke complete and truthful registrations that have been properly filed with the agency. It is for this reason that FDA's request for comment on circumstances under which a firm's registration should be revoked or considered null and void, including the process for making such determinations, somewhat troubles AFFI.

The Bioterrorism Act clearly states that failure to register in accordance with the statute is a prohibited act under the Federal Food, Drug, and Cosmetic Act ("FFDCA"). Thus, if a facility fails to register properly, or at all, it would be considered a prohibited act, the penalties for which are clear—possible injunction and/or criminal penalties imposed by a federal court. Neither the FFDCA, nor the Bioterrorism Act, authorizes the agency to revoke or nullify registrations as a penalty for any transgression of FDA's regulations.

If the agency determines that a registration form is incomplete or otherwise inadequate after FDA has processed the form and assigned a registration number, AFFI suggests the agency advise the registrant of the problem and request submission of a revised registration form. The registrant that submits a properly revised form should be able to retain the registration number originally assigned to avoid the burden of having to alert interested parties of the change. This is especially important with respect to foreign facilities that may be prone to making mistakes due to language barriers, yet must provide registration numbers to all U.S. importers of its products.

/ H.R. CONF. REP. NO. 107-481, at 134 (May 21, 2002).

V. Suggestions to Facilitate the Registration Process

While the proposed interactive Internet registration system would likely be an efficient method of gathering information from companies registering few facilities, AFFI recommends that the agency also accept transmission of electronic data files. This would allow a company operating from its headquarters location to submit a single file encompassing the required registration information for all facilities it owns, operates, or for which it is acting as an agent. The ability to submit registration data via transmission of electronic files (e.g., Microsoft Excel), in lieu of interactive data entry, would streamline the administrative burden associated with the new regulation on both the agency and larger companies.

If FDA should not allow the submission of registration forms by uploading all registration data into a single electronic format, AFFI suggests that FDA revise the regulation to provide that a company is in compliance with the registration requirement upon the agency's receipt of paper registration. We make this point to emphasize how critical it is that companies be allowed to upload their registration data in a single file. Some AFFI members have advised us that they will have to register several thousand facilities. The only conceivable way to accomplish that huge task is to allow for the submission of electronic data files. If a single file is not allowed, paper forms may be the only alternative because having one, or even several, people online filling out the forms is simply not workable in the time frame allowed. Such an approach would reduce, time, cost and data entry errors.

In the event that FDA does not allow submission of electronic data files, AFFI recommends designing the Internet-based registration system such that a company registering on behalf of multiple facilities would be able to enter registration data simultaneously from more than one desktop. Also, the system should allow a single registrant to save the data inputted in the interactive database such that information for a given facility could be partially entered one day and completed at a later date.

AFFI also believes, as noted in our initial comments to the agency, that it would be helpful for FDA and food industry trade associations, including the Institute, to work together to inform industry members about the obligation to register and the avenues for doing so. With assistance from the agency, associations could prepare and post materials discussing the registration requirement and the information that must be submitted. A question and answer document could also be developed to answer questions that are likely to arise frequently.

VI. Conclusion

In closing, AFFI thanks you for the opportunity to comment on the agency's proposal concerning registration of food facilities. AFFI looks forward to working with the agency to develop this and other required rulemakings in a manner that will maximize public health protection without unduly burdening food manufacturers, processors, and handlers or interfering with the smooth functioning of the commercial food supply.

Sincerely,

Leslie G. Sarasin

Leslie G. Sarasin
President and
Chief Executive Officer